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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

28

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/530,209

Applicant(s)

INZE ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,10,27 and 30-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10,27 and 30-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 24.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2003 has been entered.

Claims 1, 2, 4, 10, 27, 32-35 and 38-41 are newly amended.

Claims 42-47 are newly added.

Claims 1-4, 6-8, 10, 27 and 30-47 are pending.

Claims 1-4, 6-8, 10, 27 and 30-47 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Objections

Claim 42 is objected to because of the following informalities: claim 42 recites the plural "claims" in reference to claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-8, 10, 27 and 30-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed November 19, 2002.

Applicant's arguments filed March 19, 2003, have been fully considered but they are not persuasive.

Applicant argues that the amendment of claims 1 and 39 so that they no longer recite sequences encoding a protein having at least 70% sequence identity to the amino acid sequence encoded by element (a) or (b) should overcome the rejection. Applicant also points out that claims 1 and 39 have been amended to recite specific hybridization conditions. With respect to the issue of whether SEQ ID NO:1 encodes a protein that functions to activate a cyclin-dependent kinase, Applicants assert that functional testing is in progress, and that additional data to support such a function will be submitted in the form of a declaration when it becomes available. (reply pages 5-6).

The Office maintains that the claimed invention is not adequately described because the claims continue to recite sequences whose structure and function are not described. While a nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence encoding a protein of SEQ ID NO:2 have a defined structure that may be correlated with a specific biological function such as the activation of a cyclin-dependent kinase, DNA sequences hybridizing under the conditions set forth in the claims would not have a defined structure correlated with a function. The claims directed to hybridizing sequences encompass any DNA sequence of any length that would specifically hybridize with the complementary strand of a DNA sequence of SEQ ID NO:1 or a DNA sequence encoding SEQ ID NO:2. The structure and function of such a genus of sequences

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is not described. Additionally, even the recitation of a function would not overcome the rejection, because the claims encompass mutants and allelic variants that are not disclosed.

Claims 1-4, 6-8, 10, 27 and 30-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed November 19, 2002, and for the additional reasons set forth below.

Applicant's arguments filed March 19, 2003, have been fully considered but they are not persuasive.

Applicant points out that claims 1 and 39 have been amended so that they no longer recite sequences encoding a protein having at least 70% sequence identity to the amino acid sequence encoded by element (a) or (b). Applicant also points out that claims 1 and 39 have been amended to recite specific hybridization conditions. With respect to the issue of whether SEQ ID NO:1 encodes a protein that functions to activate a cyclin-dependent kinase, Applicants assert that functional testing is in progress, and that additional data to support such a function will be submitted in the form of a declaration when it becomes available. (reply page 6).

The Office maintains that the establishment of a specific biological function such as the activation of a cyclin-dependent kinase would advance prosecution at least with respect to the question of the enablement of the claimed isolated DNA sequences.

Additionally, the Office maintains that the invention is not enabled for cyclin encoding nucleic acid molecules inducible by any mitogenic agent, because the ability of any particular

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mitogenic agent to induce any particular D-type cyclin is unpredictable. A given mitogenic agent may or may not induce the expression of a particular D-type cyclin, as the induction of expression is dependent on the presence of induction-specific sequences within the promoter of the gene. For example, Soni et al. teach that the expression of Arabidopsis D-type cyclin $\delta 2$ in suspension culture cells is induced by sucrose, whereas the expression of Arabidopsis D-type cyclin $\delta 3$ is induced by cytokinin, and the expression of Arabidopsis D-type cyclin $\delta 1$ is not induced by cytokinin or sucrose (The Plant Cell, January 1995, Vol. 7, pages 85-103, see page 95, Figure 12). Here, Applicant has only taught the induction of the expression of the gene corresponding to SEQ ID NO:1 by sucrose and by cytokinin (page 36). Applicant has not taught what other mitogenic agents, if any, are also able to induce the expression of the gene corresponding to SEQ ID NO:1. Alternatively, Applicant has not identified the presence of promoter sequence motifs that would indicate that other mitogenic agents could induce the expression of the gene corresponding to SEQ ID NO:1. Because the ability of any particular mitogenic agent to induce any particular D-type cyclin is unpredictable, the induction of the expression of the gene corresponding to SEQ ID NO:1 by any mitogenic agent is not enabled.

Furthermore, the Office maintains that the invention is not enabled for modulating the plant cell cycle, plant cell division or growth by modulating the level or activity of a cyclin. The term "modulating" encompasses both increasing and decreasing the plant cell cycle, plant cell division or growth and the level or activity of a cyclin in a single method. The specification does not provide sufficient guidance for one skilled in the art to both increase and decrease the plant cell cycle, plant cell division or growth and the level or activity of a cyclin by using a single method. Additionally, it is unclear that CDC2a alone can modulate complex processes such as

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the plant cell cycle, plant cell division or growth, as processes such as the plant cell cycle, plant cell division or growth require the coordinated activity of numerous distinct proteins, and the activity of a cyclin itself is affected by the presence or absence of other proteins, such as phosphatases and its corresponding cyclin-dependent kinase.

Claims 38-39, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulating", for the reasons of record set forth in the office action mailed November 19, 2002.

Applicant's arguments filed March 19, 2003, have been fully considered but they are not persuasive.

Applicant argues that the term modulation should be interpreted as having its ordinary dictionary meaning: to adjust or regulate. Applicant also points to page 20 of the specification which provides that DNA synthesis or progression of DNA synthesis will be negatively influenced by interfering with the formation of a cyclin-dependent kinase complex, or alternatively that overexpression of the mitogenic cyclin accelerates reentry into the cell cycle. Applicant additionally points to page 21 which discloses that overexpression of a cyclin gene promotes cell proliferation, while reducing cyclin expression arrests cell division or prevents reentry into the cell cycle. Applicant further points out that part of the invention is the use of a cyclin as a positive or negative regulator of cell division.

The Office maintains that "modulating" is indefinite. With respect to the ordinary dictionary meaning of modulate, to modulate means to adjust or regulate "to a certain proportion" or "in proper measure or proportion" (See for example Webster's II New Riverside

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University Dictionary, 1994, The Riverside Publishing, or Merriam Webster Dictionary OnLine, May 2003 at <http://www.m-w.com/home.htm>, attached). Accordingly, “modulating” is a relative term, as “modulating” implies a gradual adjustment for keeping a process in “proper measure” or in “proper proportion”. Here there is no comparative basis for “proper measure” or “proper proportion”. With respect to the examples set forth in the specification, the Office maintains that such examples are not read as limiting the claims. It is suggested that the claims be amended to recite specific changes in the plant cell cycle, plant cell division or growth, and the level or activity of cyclin, in order to overcome the rejection.

Claim 2, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "enhanced", as “enhanced” is a relative term that lacks a comparative basis.

Claims 2, 38, 39, 40 and 41, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "CDC2a". It is unclear what "CDC2a" is meant to designate, as an acronym may have more than one meaning.

Claim 3, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "CDC2aAt". It is unclear what "CDC2aAt" is meant to designate, as an acronym may have more than one meaning.

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Claim 2, 4, 10, 42 and 45, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "wherein the DNA sequence encoding a cyclin is inducible by mitogenic agents". It is unclear what type of induction is intended by the claims - induction of transcription? Induction of replication? Induction of recombination? With respect to claim 45, it is also unclear whether the mitogenic agents induce the DNA sequence when it resides in the vector and in its native state, or whether the mitogenic agents induce the DNA sequence only in its native state.

Claim 4, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "obtainable", as "obtainable" is ambiguous. It is suggested that the claim be amended to recite "obtained" in order to obviate the rejection. It is also unclear whether the mitogenic agent is obtainable by the method of claim 2 or 3, or whether the isolated DNA sequence is obtainable by the method of claim 2 or 3.

Claim 27 and 37, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "means", as a "means" is not a product in a composition.

Claim 42, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "inducible", as "inducible" is ambiguous. It is suggested that the claim be amended to recite "induced" in order to obviate the rejection.

Claim Rejections - 35 USC § 101 and § 112

Claims 1-4, 6-8, 10, 27 and 30-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility, for the reasons of record set forth in the office action mailed November 19, 2002.

Claims 1-4, 6-8, 10, 27 and 30-47 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed November 19, 2002.

Applicant's arguments filed March 19, 2003, have been fully considered but they are not persuasive.

Applicant interprets the Examiner's position as being that the invention lacks utility due to insufficient evidence to establish a function for the protein encoded by the claimed isolated nucleic acids, namely activation of a cyclin-dependent kinase. With respect to this issue, Applicants assert that functional testing is in progress, and that additional data to support such a function will be submitted in the form of a declaration when it becomes available. (reply page 8).

The Office maintains that the establishment of a specific biological function such as the activation of a cyclin-dependent kinase would advance prosecution at least with respect to the question of the utility of the claimed isolated DNA sequences, as the prior art teaches the use of isolated DNA sequences encoding D-type cyclins in plants. The Office notes, however, that while a nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence encoding a protein of SEQ ID NO:2 may encode a protein with a specific biological function such as the activation of

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a cyclin-dependent kinase, DNA sequences hybridizing under the conditions set forth in the claims would not necessarily encode a functional protein, as the claims directed to hybridizing sequences encompass any DNA sequence of any length that would specifically hybridize with the complementary strand of a DNA sequence of SEQ ID NO:1 or a DNA sequence encoding SEQ ID NO:2.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 29, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

David T. Fox
for
Phuong Bui